PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference SJS:JN:FP20644	FOR FURTHER ACTION	See Form PCT/IPEA/416
International application No. PCT/AU2004/001599	International filing date *(day/month/year)* 18 November 2004	Priority date *(day/month/year)* 21 November 2003
International Patent Classification (IPC) or national classification and IPC **Int. Cl.**[7] A61 N 1/40, A61N 2/08, A61M 35/00		
Applicant INTERNATIONAL SCIENTIFIC PTY LTD		

1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.
2. This REPORT consists of a total of 4 sheets, including this cover sheet.
3. This report is also accompanied by ANNEXES, comprising:
   a. [X] *(sent to the applicant and to the International Bureau)* a total of sheets, as follows:
      [8] sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).
      [ ] sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.
   b. [ ] *(sent to the International Bureau only)* a total of (indicate type and number of electronic carrier(s)) , containing a sequence listing and/or table related thereto, in computer readable form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).
4. This report contains indications relating to the following items:
   - [X] Box No. I Basis of the report
   - [ ] Box No. II Priority
   - [ ] Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
   - [ ] Box No. IV Lack of unity of invention
   - [X] Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
   - [ ] Box No. VI Certain documents cited
   - [ ] Box No. VII Certain defects in the international application
   - [ ] Box No. VIII Certain observations on the international application

Date of submission of the demand	Date of completion of the report
24 May 2005	11 November 2005
Name and mailing address of the IPEA/AU AUSTRALIAN PATENT OFFICE PO BOX 200, WODEN ACT 2606, AUSTRALIA E-mail address: pct@ipaustralia.gov.au Facsimile No. (02) 6285 3929	Authorized Officer **PETER WEST** Telephone No. (02) 6283

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.
PCT/AU2004/001599

Box No. I Basis of the report

1. With regard to the **language**, this report is based on the international application in the language in which it was filed, unless otherwise indicated under this item.

   ☐ This report is based on translations from the original language into the following language which is the language of a translation furnished for the purposes of:

   ☐ international search (under Rules 12.3 and 23.1 (b))

   ☐ publication of the international application (under Rule 12.4)

   ☐ international preliminary examination (under Rules 55.2 and/or 55.3)

2. With regard to the **elements** of the international application, this report is based on (*replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report*):

   ☐ the international application as originally filed/furnished

   ☒ the description:

   pages **1 to 3 and 6 to 13** as originally filed/furnished
   pages* **5 and 5a** received by this Authority on **24 May 2005** with the letter of **24 May 2005**
   pages* **4** received by this Authority on **18 October 2005** with the letter of **18 October 2005**

   ☒ the claims:

   pages as originally filed/furnished
   pages* as amended (together with any statement) under Article 19
   pages* **16** received by this Authority on **24 May 2005** with the letter of **24 May 2005**
   pages* **14, 15, 17 and 18** received by this Authority on **18 October 2005** with the letter of **18 October 2005**

   ☒ the drawings:

   pages **1/3 – 3/3** as originally filed/furnished
   pages* received by this Authority on with the letter of
   pages* received by this Authority on with the letter of

   ☐ a sequence listing and/or any related table(s) - see Supplemental Box Relating to Sequence Listing.

3. ☐ The amendments have resulted in the cancellation of:

   ☐ the description, pages
   ☐ the claims, Nos.
   ☐ the drawings, sheets/figs
   ☐ the sequence listing (*specify*):
   ☐ any table(s) related to the sequence listing (*specify*):

4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).

   ☐ the description, pages
   ☐ the claims, Nos.
   ☐ the drawings, sheets/figs
   ☐ the sequence listing (*specify*):
   ☐ any table(s) related to the sequence listing (*specify*):

* *If item 4 applies, some or all of those sheets may be marked "superseded."*

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.
PCT/AU2004/001599

Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims	1-33	YES
	Claims		NO
Inventive step (IS)	Claims	1-33	YES
	Claims		NO
Industrial applicability (IA)	Claims	1-33	YES
	Claims		NO

2. Citations and explanations (Rule 70.7)

The following documents identified in the International Search Report have been considered for the purposes of this report;

D1 GB 2307862 A (JEHAN) 11 June 1997

D2 WO 2000003762 A1 (MAZAURY) 27 January 2000

D3 WO 1996015829 A2 (ADVATECH CORPORATION) 30 May 1996

Amended Claims 1-33 disclose an apparatus for facilitating transdermal delivery of therapeutic substances, said apparatus comprising: means for producing an electromagnetic field; control means arranged to control said field producing means to alternately produce active and substantially inactive electromagnetic field portions, each said active electromagnetic field portion including an electromagnetic field packet having a plurality of successive electromagnetic field pulses, each said substantially inactive electromagnetic field portion including no electromagnetic field pulses, and the time between successive electromagnetic field packets being greater than the time between successive electromagnetic field pulses.

NOVELTY

D1 discloses a patch structure (10) for transdermal therapy. D1 discloses electromagnetic impulses which are electromagnetic field portions [Abstract, page 3 line 22 - page 4 line 14].

D2 discloses a method for synergetic amplification of the standard effects of essential oil with beneficent properties for the skin and subjecting that skin to the action of pulsed high-frequency electromagnetic waves, with frequency ranging between 1 MHz and 300 MHz, with a time spacing of 0.1 to 400 milliseconds between each wave impulse [Abstract, Fig.1,2, page 6 line 6 – page 7 line 24, page 15 lines 1 -30].

D3 discloses apparatus and methods to transport medicant to human and animals through a transdermal site which is array of electromagnets with magnet control device for sequentially applying a pulse of electrical current to each electromagnet in array to generate magnetic field along the array thereby inducing a direct electric field within the material [Abstract, Fig. 15, 16, page 3 line 31 – page 4 line 6, page 6 lines 29 – 35, page 15 line 25 – page 17 line 30].

None of D1, D2 or D3 discloses the feature of the time between successive electromagnetic field packets being greater than the time between successive electromagnetic field pulses.

Therefore the subject matter of claims 1 to 33 is new and meets the requirements of Article 33(2) PCT with regard to novelty.

[Continued in Supplemental Box]

Supplemental Box

In case **the space in any of the preceding boxes is not sufficient.**

Continuation of: V

Inventive Step (IS)

The claimed invention is not obvious in the light of any of the cited documents nor is it disclosed in any obvious combination of them. It is also considered that it would not be obvious to a person skilled in the art in the light of common general knowledge either by itself or in combination with any of these documents.

Therefore the subject matter of claims 1 to 33 is not obvious and meets the requirements of Article 33(3) PCT with regard to inventive step.

In one arrangement, the duration of each energisation signal pulse is between 1μs and 1s, more particularly between 25μs and 100ms.

The apparatus may take the form of a generally flat member having the means for producing an electromagnetic field and the control means embedded therein.

In one arrangement, the therapeutic substance is disposed on a surface of the apparatus. The therapeutic substance may be a drug, vaccine, ion, macromolecule, DNA fragment, gene or any other substance desired to be passed through the skin of a patient for the purpose of obtaining a beneficial effect.

In accordance with an alternative aspect of the present invention, there is provided a method of transdermally delivering therapeutic substances, said method comprising:

producing an electromagnetic field;

directing the electromagnetic field at a desired treatment area of a patient's skin; and

controlling the electromagnetic field so as to alternately produce active and substantially inactive electromagnetic field portions, each said active electromagnetic field portion including an electromagnetic field packet having a plurality of successive electromagnetic field pulses, each said substantially inactive electromagnetic field portion including no electromagnetic field pulses, and the time between successive electromagnetic field packets being greater than the time between successive electromagnetic field pulses.

Brief Description of the Drawings

The present invention will now be described, by way of example only, with reference to the accompanying drawings, in which:

Figure 1 is a diagrammatic perspective view of a portion of a stratum corneum prior to application of an

an electromagnetic field packet having a plurality of successive electromagnetic field pulses, each said substantially inactive electromagnetic field portion including no electromagnetic field pulses, and the time between successive electromagnetic field packets being greater than the time between successive electromagnetic field pulses.

In one arrangement, the means for producing an electromagnetic field includes a coil. The means for producing an electromagnetic field may further include a solid state switching device which may be a transistor such as a bipolar transistor connected in series with the coil.

In one arrangement, the control means is arranged to produce an energisation signal useable to control switching of the solid state switching device, the energisation signal including a repeating energisation signal packet, each energisation signal packet including a plurality of energisation signal pulses of generally rectangular configuration.

The control means may comprise a microcontroller which may be programmable by a user. The microcontroller may be programmed such that dermal permeability is increased at one or more specific times, permeability is increased for a specific period of time, and so on.

In one embodiment, the energisation signal packet repeats at a frequency of between 1Hz and 100Hz, more particularly between 10Hz and 50Hz.

In one arrangement, each energisation signal packet includes between 12 and 20 energisation signal pulses.

14. Apparatus as claimed in any one of the preceding claims, wherein the duration of each energisation pulse is between 1μs and 1s.

15. Apparatus as claimed in claim 11, wherein the duration of each energisation pulse is between 25μs and 100ms.

16. Apparatus as claimed in any one of the preceding claims, wherein the apparatus comprises a substantially flat member having the means for producing an electromagnetic field and the control means embedded therein.

17. Apparatus as claimed in any one of the preceding claims, wherein the therapeutic substance is disposed on an outwardly facing surface of the apparatus.

18. Apparatus as claimed in any one of the preceding claims, wherein the therapeutic substance is a drug, vaccine, ion, macromolecule, DNA fragment or gene.

19. A method of transdermally delivering therapeutic substances, said method comprising:

producing an electromagnetic field;

directing the electromagnetic field at a desired treatment area of a patient's skin; and

controlling the electromagnetic field so as to alternately produce active and substantially inactive electromagnetic field portions, each said active electromagnetic field portion including an electromagnetic field packet having a plurality of successive electromagnetic field pulses, each said substantially inactive electromagnetic field portion including no electromagnetic field pulses, and the time between successive electromagnetic field packets being greater

CLAIMS:

1. An apparatus for facilitating transdermal delivery of therapeutic substances, said apparatus comprising:

means for producing an electromagnetic field;

control means arranged to control said field producing means to alternately produce active and substantially inactive electromagnetic field portions, each said active electromagnetic field portion including an electromagnetic field packet having a plurality of successive electromagnetic field pulses, each said substantially inactive electromagnetic field portion including no electromagnetic field pulses, and the time between successive electromagnetic field packets being greater than the time between successive electromagnetic field pulses.

2. Apparatus as claimed in claim 1, wherein the means for producing an electromagnetic field comprises a solid state switching device.

3. Apparatus as claimed in claim 2, wherein the control means is arranged to produce an energisation signal useable to control switching of the solid state switching device, each energisation signal packet including an active energisation signal portion including a plurality of energisation signal pulses and a substantially inactive energisation signal portion including no signal pulses.

4. Apparatus as claimed in claim 3, wherein at least some of the signal pulses are of generally rectangular configuration.

5. Apparatus as claimed in any one of the preceding claims, wherein the means for producing an electromagnetic field includes a coil.

6. Apparatus as claimed in any one of claims 2 to 4, wherein the solid state switching device comprises a transistor.

7. Apparatus as claimed in any one of the preceding claims, wherein the control means comprises a microcontroller.

8. Apparatus as claimed in claim 7, wherein the microcontroller is programmable by a user so that an electromagnetic signal corresponding to a predetermined therapeutic substance delivery plan is produced.

9. Apparatus as claimed in claim 8, wherein the microcontroller is programmed such that dermal permeability is increased at one or more specific times.

10. Apparatus as claimed in claim 8 or claim 9, wherein the microcontroller is programmed such that dermal permeability is increased for a specific period of time.

11. Apparatus as claimed in any one of the preceding claims, wherein the energisation signal packet repeats at a frequency of between 1Hz and 100Hz.

12. Apparatus as claimed in claim 11, wherein the energisation signal packet repeats at a frequency of between 10Hz and 50Hz.

13. Apparatus as claimed in any one of the preceding claims, wherein each energisation signal packet includes between 12 and 20 energisation signal pulses.

than the time between successive electromagnetic field pulses.

20. A method as claimed in claim 19, wherein the step of controlling the electromagnetic field comprises producing an energisation signal useable to control switching of a solid state switching device, each energisation signal packet including an active energisation signal portion including a plurality of energisation signal pulses and a substantially inactive energisation signal portion including no signal pulses.

21. A method as claimed in claim 20, wherein at least some of the signal pulses are of generally rectangular configuration.

22. A method as claimed in any one of claims 19 to 21, wherein the step of producing an electromagnetic field comprises energizing a coil.

23. A method as claimed in claim 20 or claim 21, wherein the solid state switching device comprises a transistor.

24. A method as claimed in any one of claims 19 to 22, wherein the control means comprises a microcontroller.

25. A method as claimed in claim 24, further comprising the step of programming the microcontroller so that during use an electromagnetic signal corresponding to a predetermined therapeutic substance delivery plan is produced.

26. A method as claimed in claim 25, further comprising the step of programming the microcontroller such that dermal permeability is increased at one or more specific times.

27. A method as claimed in claim 25 or claim 26, further comprising the step of programming the microcontroller such that dermal permeability is increased for a specific period of time.

28. A method as claimed in any one claims 19 to 27, wherein the energisation signal packet repeats at a frequency of between 1Hz and 100Hz.

29. A method as claimed in claim 28, wherein the energisation signal packet repeats at a frequency of between 10Hz and 50Hz.

30. A method as claimed in any one of claims 19 to 29, wherein each energisation signal packet includes between 12 and 20 energisation signal pulses.

31. A method as claimed in any one of claims 19 to 30, wherein the duration of each energisation pulse is between 1μs and 1s.

32. A method as claimed in claim 31, wherein the duration of each energisation pulse is between 25μs and 100ms.

33. A method as claimed in any one of claims 19 to 32, wherein the therapeutic substance is a drug, vaccine, ion, macromolecule, DNA fragment or gene.